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SUBJECT: HUMAN SUBJECTS PROTOCOL NO. HS-03-021

Under review is the Human Subjects Protocol No. HS-03-021, entitled *Influence of Moisture on the Transferability of Malathion Applied on Strawberries*. This protocol was submitted to this Branch for approval on March 18, 2003 by Dr. Robert I. Krieger of the University of California at Riverside (UCR). As reflected in its title, the study is aimed to investigate the influence of naturally occurring moisture on the transferability of malathion residues from strawberry foliage onto the fieldworker's body or clothing. The greater part of this study will involve the collection of urine samples from strawberry pickers and the measuring of the malathion metabolites in the collected urine samples. Foliar samples will also be collected and then measured for residue levels. The Institutional Review Board (IRB) at UCR approved this protocol on March 10, 2003.

This present review supports the *conduct* of the study since its results are expected to have a significant impact on the assessment of reentry exposure for malathion or other pesticide use in the field. The test subjects (workers) will not be at any (additional) risk in this study in part because they will be more than 17 years old with some experience in picking strawberries. However, the greater assurance of worker safety actually comes from the fact that the amount of malathion foliar residues that the participants will be exposed to will be at or below the regulatory limit, as the pesticide supposedly will be sprayed at or below the maximum label rate. And according to the protocol, the workers will pick the treated strawberries under normal work conditions at an allowed reentry interval. In this and other similar cases, urine collection from human subjects is a matter of inconvenience and violation of privacy, not an issue of safety.

This present review nonetheless considers the submission as more a research plan than a routine study protocol largely because several elements basic to the latter are lacking. For example, the analytical methods and the particular (or anticipated) malathion product to be used were not provided in the initial submission. Upon request, these additional pieces of information were later submitted to this Branch via email on May 4, 2003. The provision of these basic elements would undoubtedly gain a greater chance for assurance or commitment up front from a reviewing party in their accepting the study results. Yet it is important to note that the lack of these basic elements *per se* cannot directly or immediately denounce the importance of the study. Nor can it be an indication that there is a potential for some (additional) harm to the test subjects. Insofar as no (additional) harm to the participants will be incurred and the study data are not intended for use by the reviewing party, there does not seem to be a need for the reviewing party to have a fuller comprehension of the methodology or of the study procedures involved.

cc: James R. Goodbrod, DVM